510(k) Summary

Submitter:	Zimmer Trabecular Metal Technology, Inc. MAR - 4 2010 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Kathleen Rutherford Associate Director, Regulatory Affairs Telephone: (973) 576-0139 Fax: (973) 884-8792
Date:	September 15, 2009
Trade Name:	Trabecular Metal™ Vertebral Body Replacement System Instrumentation Set
Common Name:	Vertebral Body Replacement Device Instrumentation Set
Classification Name and Reference:	Spinal Intervertebral Body Fixation Orthosis 21 CFR § 888.3060, MQP

DEVICE DESCRIPTION

The existing, commercially available Trabecular Metal Vertebral Body Reconstruction System is intended for use in thoracolumbar (T1-L5) surgical cases to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Trabecular Metal Vertebral Body Reconstruction System is wholly comprised of Trabecular Metal Porous Tantalum (tantalum deposited on a vitreous carbon skeleton) and is available in a variety of configurations to accommodate the anatomical requirements of different patients.

The Trabecular Metal Vertebral Body Replacement System Instrumentation Set which is the subject of this premarket notification is intended for use in these thoracolumbar surgical cases and facilitates the implantation of the Trabecular Metal Vertebral Body Replacement implant system. The provisionals size the surgical site in order to determine the appropriate TM-400 implant size. The straight inserter and tamp facilitate implantation of the TM-400 implant via anterior or lateral lumbar approach. All instruments included in the set are made from 17-4 stainless steel.

INDICATIONS FOR USE

The Trabecular Metal Vertebral Body Replacement System is comprised of vertebral body replacement devices intended for use in thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Trabecular Metal Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Trabecular Metal Vertebral Body Replacement may be used with bone graft.

DEVICE TECHNOLOGICAL CHARACTERISTICS AND COMPARISON TO PREDICATE DEVICE(S)

Zimmer Trabecular Metal Technology, Inc. has submitted documentation demonstrating the substantial equivalence of the proposed instrument set to its predicate devices. The subject instrument set is similar to its predicate devices with respect to intended use/indications for use, materials, and basic principles of operation.

PERFORMANCE DATA

The results of testing and analyses conducted demonstrate that the worst cases of the proposed instruments adequately meet the predetermined requirements established for its mechanical performance.

SUBSTANTIAL EQUIVALENCE

The redesigned Trabecular Metal™ Vertebral Body Replacement System Instrument Set is substantially equivalent to the predicate instruments with respect to intended use/indications for use, technological characteristics and basic principles of operation. As demonstrated by supporting tests and descriptions, this minor redesign does not present any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR - 4 2010

Zimmer Trabecular Metal Technology, Inc
% Ms. Kathleen Rutherford
Associate Director, Regulatory Affairs
10 Pomeroy Road
Parsippany, New Jersey 07054

Re: K093127
Trade/Device Name: Trabecular Metal Vertebral Body Replacement System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: MQP
Dated: February 23, 2010
Received: February 25, 2010

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093127

Device Name: Trabecular Metal™ Vertebral Body Replacement System Instrument Set

Indications for Use:

The Trabecular Metal Vertebral Body Replacement System is comprised of vertebral body replacement devices intended for use in thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Trabecular Metal Vertebral Body Replacement is intended for use with supplemental internal spinal fixation systems. The Trabecular Metal Vertebral Body Replacement may be used with bone graft.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093127

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